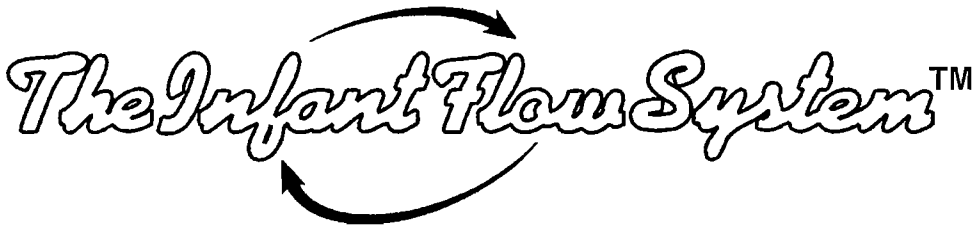

Mk II Infant Flow™ Driver

Models M672B and M672P

Software Versions: V1.22 and all V2.xx

Service Manual

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CE 0120

Contents

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1 - About this Manual

To assist the engineer and technician this manual provides detailed descriptions of the major components of the M672B and M672P versions of the Infant Flow™ Driver from serial number 2000 up. For Drivers with serial numbers below 2000, refer to document M672SM. We suggest that all personnel involved in the service, repair or re-calibration of these products fully familiarise themselves with the clinical aspects and usage of the Infant Flow™ System as this will assist in front line troubleshooting and service. This manual must be used in conjunction with the Operating Manual document numbers 672-830 (English, Arabic, Dutch, French and German), 672-831 (English, Danish, Finnish, Norwegian and Swedish), 672-832 (English, Greek, Portuguese, Spanish and Italian) or 672-833 (English, Chinese, Japanese and Turkish).

Routine maintenance, service or repair of the EME Infant Flow™ Driver as defined in this manual should only be undertaken by competent qualified individuals trained in the calibration, service and repair of devices of this nature and who have access to the special tools and equipment that are required. Alternatively contact EME or an authorised distributor to ensure full reliability and safety of the product.

Defective or worn parts must be replaced only with parts manufactured, sold or approved by E.M.E. (Electro Medical Equipment) Ltd..

The manual comprises several discreet sections, which deal with the major sub-assemblies in order. This allows work to be undertaken in a logical and methodical manner on one section of the product without disturbing other parts. However, we recommend that the complete performance and verification procedure be carried out after any work has been carried out on any part of the Infant Flow™ Driver.

E.M.E. (Electro Medical Equipment) Ltd. has a policy of continual improvement and update of all products. Technical bulletins are sent to all registered users of the company's products to keep them informed of any product changes. We welcome suggestions from users for product improvement and enhancement - please write to the either the Marketing or Research & Development departments with your comments.

2 - Product Specification

- **Gas Supply** - Nominal 4 bar, clean, dry medical air and oxygen.
- **Range** - Minimum 2 bar, maximum 6 bar. Maximum differential pressure 2 bar.
- **Power Supply** – M672B - 200 to 265VAC, 0.10A, or 95 to 135VAC, 0.20A, 50 to 60Hz.
- **Power Supply** – M672P – 12VDC, 1A from approved AC adaptor (see approved accessories list on page 28 for options), Internal 12V Lead/Acid Battery - The battery has a life of four (4) hours from a full charge with fifteen (15) minutes remaining after the low battery indicator illuminates.

  Note: It can take up to sixteen (16) hours to recharge a fully discharged battery.
- **Weight** – M672B - 6.2Kg
  M672P - 5.6Kg
- **Dimensions** – 212x170x140mm (excluding gas inlets, patient outlets and mounting brackets).
- **Air/Oxygen Mixer** - Range 21 to 100% oxygen, accuracy ±3% of selected output.
- **Flowmeter** - Range 0 to 15 lpm, accuracy ±10% of selected output.
- **Auxiliary Outlet** - Mixed gas outlets, several types available dependant on model, all optional.

  M672B - DISS underside mounted or Mini-Schrader Quick Connect underside mounted, both with integral check valve and 15 lpm capability.

  M672P - DISS side mounted or Quick Connect front panel mounted, both with integral check valve and 15 lpm capability.
- **Pressure Relief** - 2 systems fitted

  1 Patient safety - automatic electronic valve system preset to vent to ambient at 11cm H_2O.

  2 System/delivery circuit safety - mechanical internal relief valve preset at 205cm H_2O.
- **Manometer** - Range, 0 to + 12cm H_2O, accuracy ±1cm H_2O.
- **Oxygen Monitor** - Range 0 to 100% oxygen, accuracy ± 2% of span.
- **Alarm System** - Four separate alarm systems are provided all of which are automatic, the electronic alarms are set after 2 minutes operation without operator intervention although the operator can manually set or reset them if required.

  1 Supply gases failure - If the differential pressure between the two inlet gases falls outside of the limit of 2 bar or one gas fails completely an alarm will sound and the gas at the higher pressure only will be delivered to the patient.

  2 High patient pressure - An audible and visual high pressure alarm is preset at 11cm H_2O. This alarm automatically activates a pressure relieving solenoid which instantly reduces the pressure in the patient circuit to zero. The pressure is restored after 3 seconds but will be reduced to zero should the cause of the alarm condition still exist. A second high pressure alarm with audible and visual indication is set 3cm H_2O above the measured CPAP pressure.

  3 Low patient pressure - An audible and visual low pressure alarm is set at 2cm H_2O below the measured CPAP pressure or at 0 cm H_2O if this would otherwise be negative.

  4 Failure to deliver correct oxygen concentration - Audible and visual alarms are provided at ± 5% of

the measured FiO_2 at the time of arming of the alarm with an upper maximum limit of 101% and a lower minimum limit of 20%. There is a low hazard warning at 18% oxygen or below.

- **EN 60601-1 Classification**

  M672B - Class 1, Type B, IPX 0

  M672P - Internally Powered Equipment, Type B, IPX 0

  This equipment is rated for Continuous Operation.

- **Storage Conditions -**

  Safe for storage at 0° to 50°C.

  Relative humidity 90% non-condensing.

  Atmospheric pressure 0.6 to 1.4 Bar.

- **Minimum Shipping Temperature** - 0°C

- **Operating Environment** - 10° to 40°C

- Keep dry and do no expose to direct sunlight.

- This product meets the EMC requirements of EN60601-1-2.

NOTE - Although the Infant Flow™ driver meets the requirements of current EMC/RFI legislation this does not guarantee immunity from all sources of radiated energy. Some mobile telephones and other products containing radio transmitting components may cause malfunction of the Infant Flow™ driver and should not be used in the vicinity of the device.

NOTE - All of the functional accessories supplied by EME for use with the Infant Flow™ driver are for single patient use only. These accessories include the Infant Flow™ generator, delivery breathing circuits, humidification chambers, silencer/bacteria filters and fixation bonnets.

Under no circumstances should sterilisation or re-use of these products be attempted. Please see the disclaimer on page 22 of this manual.

3 - Performance Verification Procedure

This performance verification procedure provides a means of determining whether the EME Infant Flow™ Driver meets its design specifications. These tests are intended to be performed in the Hospital by qualified personnel. The procedure should be performed at least every four months or more frequently if desired or if the device is suspect.

The check list must be followed exactly and if the Infant Flow™ Driver fails to meet any specifications it should be removed from service until calibration and/or service is accomplished. Please note that should electrical safety tests be performed the M672P is an internally powered device and should not be subjected to tests with equipment such as a Rigel tester.

NOTE: It is recommended that hospital personnel responsible for the Performance Verification Tests maintain records of their activities and identify equipment authorised for use.

WARNING: Oxygen vigorously accelerates combustion. To avoid explosion hazard do not use any instrument or other equipment that may have been exposed to mineral oil or grease contamination.

The performance verification procedure is divided into three tests, the first for the air/oxygen mixer, the second for the pressure manometer and the third for the oxygen analyser.

The following special equipment is necessary to perform the tests fully, a manometer (e.g. Timeter RT200) accurate to ± 0.2 cm H_2O, adjustable pressure regulators, a calibrated oxygen analyser accurate to ±1% and a typical breathing circuit with an Infant Flow™ Generator and prongs attached. Do not attempt to perform the tests without suitable equipment.

First Test - Air/Oxygen Mixer

Observe the air inlet filter. If this is dirty or wet it should be replaced.

Connect the Infant Flow™ Driver to supply gases which are adjustable from 0 to 4 Bar or more. EME supply regulator sets to suit most pipeline systems. Please request ordering information from the customer services department.

Overall Accuracy - Set both supply gas pressures to 4 Bar. Select a flow of 8 lpm on the Flowmeter.

Compare the oxygen analyser readings to mixer settings of 21, 40, 60, 80 and 100%. The mixer has a specified accuracy of ± 3%. If the oxygen analyser is accurate to within ± 1% the setting and the analyser should agree within ± 4% at the various settings.

Accuracy with varying inlet pressures - Select 60% and observe the reference oxygen analyser reading obtained with equal inlet pressures (4 Bar each). Vary the inlet pressures to the mixer to 3 Bar oxygen and 4 Bar air and then 4 Bar oxygen and 3 Bar air. Note the oxygen analyser reading at each extreme and verify that the oxygen reading does not vary by more than 3% at each extreme.

Alarm module test - Starting with the oxygen and air supplies at 4 Bar and 60% (the alarm should be silent) reduce the air inlet supply to 2 Bar or just under. The alarm should sound and the oxygen analyser should read 100%. Increase the air supply pressure slowly, the alarm should cut out at around the 3 Bar level. Repeat the procedure varying the oxygen pressure. When the alarm sounds the oxygen analyser reading should drop to 21%.

Second test - Oxygen Analyser

Set the mixer to 21% and the flowrate to 8 lpm. Observe that the oxygen reading is stable at 21% after one minute. If it is not adjust the lower potentiometer accessible from the left-hand side of the driver to obtain a reading of 21%.

Set the mixer to 100% and observe that the oxygen reading is stable at 100% after one minute. If it is not adjust the upper potentiometer accessible from the left-hand side of the driver to obtain a reading of 100%. If adjustments are found to be necessary repeat this procedure two or three times as there may be some small interaction between the controls.

Once the end point calibration is satisfactory set the mixer to 60% and check that the analyser reads between 57 and 63%.

Third Test - Pressure Manometer

Tee the test manometer with the hand pump bulb in line into the pressure input port on the front panel of the Infant Flow™ Driver. Check that both the bar graph manometer and the test manometer are at zero then inflate the system to 10 cm H_2O and observe that the bar graph manometer display illuminates and indicates 10 cm H_2O. If it doesn't, refer the device for full calibration.

Reduce the pressure by 1 cm H_2O at a time and ensure that the bar graph manometer tracks the pressure.

Fourth Test - Alarm Functions

Attach the delivery circuit and Infant Flow Generator to the Infant Flow Driver. Set the flow to 8 lpm, occlude the prongs and check that the bar graph manometer shows 5 cm H_2O. Press the Arm/Mute button for 3 seconds to set the alarms and then occlude the exhaust tube of the Infant Flow Generator to create an over-pressure above 11 cm H_2O, at this point all of the LED's in the bar graph illuminate, the pressure vent valve operates immediately releasing the pressure to near zero and the alarm sounds.

Remove the occlusion to the exhaust tube and press the Arm/Mute button for 3 seconds to reset the alarms. Remove the occlusion to the prongs allowing the pressure to drop to zero. Observe that the low pressure alarm activates immediately. Press the Arm/Mute button once, this will silence the alarm. Occlude the prongs again to restore the pressure to 5 cm H_2O and observe that the visual alarm cancels.

Increase the flow to set the pressure to 8 cm H_2O and observe that the high alarm activates after 15 seconds. Reduce the flow to drop the pressure to 3 cm H_2O and observe that the high alarm cancels and that the low alarm activates after 15 seconds.

If any of the above alarm functions fail to perform refer the driver for full service and calibration.

4 - Routine Maintenance

Routine maintenance of the Infant Flow™ Driver is limited to regular checking of the oxygen analyser calibration and periodic (4 monthly) checking of the calibration of the air/oxygen mixer and Electronic pressure manometer, status of the gas inlet filters, integrity of the alarm systems and cleaning of the exterior surfaces.

We recommend annual replacement of all filters, silencers, certain "O" rings and the oxygen fuel cell. Service kits containing all necessary parts are available for all models of the Infant Flow™ Driver. See the spare parts list Appendix D on page 35 for the appropriate kit to suit your driver.

An Infant Flow™ Driver in need of re-calibration, service or repair must not be used until the necessary procedures are performed and the equipment has been tested to ascertain that it is functioning correctly.

The exterior air filter can be observed through the polycarbonate bowl. If it is discoloured or wet it should be replaced. A special tool (part number Mxxxxxx) is supplied with the M672P driver to facilitate easy removal of the bowl.

CAUTION: The precision gas mixing device incorporated in this product may become non-functional or damaged if used without the protective water trap and filters provided.

Oxygen Analyser Calibration

The integral oxygen analyser is of the fuel cell type and as such requires a regular calibration check. To perform this check set up the Infant Flow™ Driver as for use and allow a minute for stabilisation of the device. Select an oxygen concentration of 21%, wait one minute and verify that the display indicates 21. If not, remove the small white plug adjacent to the 21% mark on the side if the device and adjust the potentiometer to give a reading of 21. Set the mixer to 100%, wait one minute and verify that the display indicates 100. If not, remove the small white plug adjacent to the 100% mark on the side of the device and adjust the potentiometer to give a reading of 100. Return the mixer to the 21% position and verify that the display reads 21%. There may be some small interaction between the set point controls if a gross adjustment is required, the process may need to be repeated two or three times. If this is the case it is indicative that the fuel cell is wearing out and should be replaced. Refer the Infant Flow™ Driver to a competent service authority for replacement of the fuel cell. Once calibration is completed please replace the white plugs.

Changing the Oxygen sensor

The oxygen sensor must be changed annually or when calibration is no longer possible. In all versions of the M672 Infant Flow™ Driver the sensor is located in the mechanical section immediately behind the flowmeter. Methods of access vary dependant on the model. In all cases ensure that the Infant Flow™ Driver is disconnected from the power input supply.

M672B - To gain access remove the top cover of the enclosure. This is achieved by removing the four M3 x 6mm instrument head screws (2 on each side), the top cover can then be lifted off. Remove the four M3 x 8mm pan head screws on the rear cover and the remaining two M3 x 6mm instrument head screws on the electronic module. Disconnect the grounding straps and slide the module forward to facilitate easy removal of the oxygen sensor. Carefully remove the electrical connector from the old cell by using a small blade screwdriver to release the locking clip and unscrew the oxygen sensor from the flowmeter mounting block.

M672P - Remove the three M4 screws on the bottom of the Driver, the M4 screw on the rear of the Driver together with the M3 screw in the top left rear panel. The entire mechanical assembly may now be pulled forward to facilitate easy removal of the oxygen sensor. Carefully remove the electrical connector from the old cell by using a small blade screwdriver to release the locking clip and unscrew the oxygen sensor from the flowmeter mounting block.

The new oxygen sensor must be carefully screwed into the block, ensure that the O-ring is fitted before screwing in. Fit the electrical connector into the new sensor observing the polarity. Re-assemble the Infant Flow™ Driver, apply the air and oxygen and switch on the power. Allow two hours for the oxygen sensor to stabilise before performing the full two-point calibration. Return the Infant Flow™ Driver for use with patients only after calibration is satisfactory.

Dependant on storage and shipping conditions it is known that the output of galvanic oxygen fuel cells may drift for the first few days of use and it is recommended that the calibration is checked daily for the first three days after a new sensor is fitted.

Cleaning

The exterior surfaces of the Infant Flow™ Driver can be cleaned with a mild soap or liquid disinfectant solution. Do not use cleaning agents that contain abrasives.

Always disconnect the Infant Flow™ Driver from the power input supply before cleaning.

CAUTION: Do not immerse any part of this device in water or gas or steam sterilise it. Damage will result.

5 - Electrical and Electronic Description

M672B Power Supply – The M672B incorporates a multi-tapped transformer with a voltage selector which can be set to suit a range of input voltage conditions. Voltage selection is made by lifting a flap under the fuseholder and sliding the tray out. The voltage selector may then be withdrawn and refitted as required to suit the mains voltage available. Four settings are provided, these are 100V, 120V, 220V and 240V.

M672P Power Supply – The M672P is a battery operated instrument which incorporates a 12 volt sealed lead acid battery and integral battery charger. The power switch on the rear panel only switches the power to the electronics and not the external power to the battery charger circuitry. This enables the Infant Flow™ driver to be switched off whilst also allowing the battery to remain on charge. A fully charged battery will enable the Infant Flow™ Driver to operate independently for at least 4 hours.

NOTE: It is essential that the M672P be connected to an external power source whenever possible and within 20 minutes of the red low battery indicator illuminating. Should the power switch not be turned off or the external power not be applied the battery will continue to discharge even after the Infant Flow™ Driver has ceased to operate.

The charger is capable of recovering a totally discharged battery but this could take up to 16 hours depending on the level of discharge. It should however be noted that once an external power source is connected the unit will perform perfectly even though the full battery backup facility may not be available for an extended time period.

Display - The display and processor board are mounted as a pair on the front panel. The signals to the display board are routed through the 40 way connector CON1. The pressure bar graph, D13 to D26 and the "Alarms Armed" LED's D18, are driven by IC3, a MM5450N LED driver. The alarm LED's, D11, D27, D2 and D5 are driven by IC2, a UCN5812A. The seven segment oxygen concentration displays, LD1 to LD3, are driven by IC1, an ICM7212AMIPL display driver. Also fitted on the display board is the "ARM/MUTE" push button, SW1, and a NORP12 light dependant resistor, LDR1, for the auto-dimming of the displays. The luminous intensity for the displays is controlled by a signal derived from LDR1. The two display drivers require different signals to change the brightness of the displays. To accomplish this two op-amp circuits are provided on the processor board.

The M672P Display board has three additional LED's fitted which are the battery status indicators. These are connected to the power supply board with a 5 way lead.

Processor - The processor board fits behind the display board and is connected to it by a 40 way connector, CON1. The instrument is based around a Motorola 68705 type micro-controller IC1. This device is one time programmable and, should it become defective, can only be replaced with a pre-programmed device obtained from EME or an authorised distributor.

The micro-controller contains the following elements:

- 6805 Micro Computer
- 24 bi-directional I/O Lines
- 8 Input Only Lines
- 4 Channel Analogue to Digital Converter
- 3776 Byte Programmable Read Only Memory
- 112 Byte Random Access Memory
- 8 Bit Timer
- 7 Bit Pre-Scaler
- Memory Mapped I/O

The Microprocessor clock signal is generated by XTL1 and C2, a 4 MHz external crystal and capacitor. There is no provision for adjusting the frequency of the oscillation.

The pressure sensor PT1, is a Sensym solid state device having a range of 0 to 1 PSI which is fitted directly to the processor board. It can withstand up to 20 PSI without sustaining damage. This item is not a standard component as it is specially selected to our specification for low noise and zero temperature drift. It must only be replaced with a device to the same specification obtained from EME or an authorised distributor.

The reference section of the LM10, IC7, produces 200 mV which is amplified by the op-amp section of IC7 to produce 12 V to energise the pressure sensor. The AMP02, IC6, provides the signal conditioning for the pressure sensor with potentiometer VR3 being used to adjust the stage gain. Stage 1 of IC5, a LM324, is used in conjunction with VR7 to swing the output of the APM02 so that any offset can be trimmed out. The amplified output from the pressure sensor circuit is applied to the analogue input AN0 of the micro-controller. In parallel with this signal is IC4, a Thomson L9700 or Texas Instruments TL7726 precision clamp. This ensures that the inputs to the micro-controller cannot go outside the limits of the ADC reference.

On the M672B only input AN1 on IC1 is used for the signal conditioned mixer monitor potentiometer. The mixer monitor PCB is mounted on the front panel of the mixer unit. The potentiometer is used to monitor the oxygen control shaft position. It is connected between 0V and 5V and feeds an output of a proportion of this depending upon where the mixer shaft is set. Stage 1 of IC8, an LM324 quad op-amp, amplifies the signal and IC8 stage 2, provides an offset to ensure that the output achieves a level of 0.05V at 21% O_2 and 5V at 100% O_2. VR6 adjusts the offset and VR5 sets the span. This section of the electronics is used for determining the oxygen alarm limits, IC4 is again used to clamp the signal to the micro-controller. On the M672P the alarms are set on the measured oxygen value. Input AN2 on IC1 is used for the oxygen monitor. IC8 stage 4 provides an offset to trim out any zero error from the oxygen sensor, whilst stage 3 provides the necessary amplification. VR8 adjusts the offset and VR4 adjusts the gain. IC4 is used to clamp the signal. Input AN4 on IC1 is spare and is connected to ground to prevent noise pick-up from getting into the measurement circuitry. On the M672P input AN1 is also spare and is tied to ground in a similar fashion.

The display brightness levels are generated from the NORP12 signal fed back from the Display Board. A resistive circuit, VR2 and R11, is used to set the overall brightness level and the fed-back signal modulates this. The brightness of the 7 segment displays is set by the difference between this level and 15V. The brightness of the bar graph LED's is adjusted by using trimmer VR1 to set a constant current dependant upon the voltage at its wiper. IC5 stage 3 and transistor TR2 form a voltage controlled constant current source.

The audible alarm is fitted on the Processor Board and is driven by the micro-controller via MOSFET TR1. The audible alarm is powered from the +15V rail and is a high efficiency type, selected for its high output at low voltages.

An over-pressure relief valve is fitted in the Infant Flow™ Driver to vent any excessive pressures to atmosphere. This slave over-pressure valve is driven by the micro-controller using a solenoid valve as a master. The power source for the solenoid valve is a three terminal regulator, REG1, connected as a constant current source. The solenoid valve is operated by a MOSFET, TR3, connected in series with opto-coupler, IC9, to monitor the function of the solenoid valve circuit.

Also fitted on the Processor Board is a two-stage watchdog circuit. The first stage, IC2, is a Silicon General SG3548N which has four sense inputs, an inverter and a threshold input. The inverter is connected so as to allow monitoring of the minus 15V power rail by Sense 4 input. The 5V and 15V power rails are monitored by Sense 2 and Sense 3 inputs respectively. The Sense inputs are checked for voltages both over and under the set levels. The tolerance on the over and under voltages is set by using the threshold input. The resistors, R6 and R8, set the window width to plus and minus 5%. The line input, which is normally used to monitor an AC input, is used here to gate the watchdog reset pulses from the micro-controller with the power supply monitor signal to produce outputs at pins 7, 9 and 10. Whilst all is well, this pulsating signal is applied to IC3 pin 6 to prevent timing out of the watchdog. IC3 is a Maxim MAX694CPA, Supertex MP694P or an AMD AD694AN microprocessor supervisory circuit, of which only the 1.6 second timer is used. If any power rail goes above its permitted value, the O/V output at pin 9 will go low; if any power rail goes below its permitted value, the U/V output at pin 10 will go low. In either case, the watchdog reset pulses will be interrupted and the micro-controller will reset after 1.6 seconds delay. C12 provides a short delay on operation of the sense inputs to avoid operation on transients.

M672B and M672P Electronics Trouble Shooting Guide		
Problem or fault	Possible cause	Corrective action
M672B - The electronic module does not function at all	No mains power	Power cord connected?
	Power supply fault	Mains switch turned on?
		Voltage selector set correctly?
		Check primary fuses
		Check plug fuse (if fitted)
		Power connector plugged in?
M672B - Electronic module continually resetting	+ 5 VDC supply faulty + 15VDC supply faulty - 15 VDC supply faulty	Check PSU secondary fuses, BR1/BR2 bridge rectifiers and voltage regulators
M672P - The electronic module does not function att all	Battery discharged	External power source connected?
	Power supply fault	External power source switch turned on?
		Check primary fuses
M672P - Electronic module continually resetting	+ 5 VDC supply faulty + 15VDC supply faulty - 15 VDC supply faulty	Check PSU fusible link and DC to DC converters
All displays dim	Auto dimming circuits faulty or not set correctly	Check VR1, VR2, LDR1 and IC5
Audio alarm works but visual does not	Alarm LED's defective	Check alarm LED's
Visual alarm works but buzzer does not	Buzzer faulty	Check buzzer
	Buzzer drive circuit faulty	Check TR3 (ZVN4306A)
Manometer display off	Faulty display driver	Check IC2 (MM5450N)
Parts of manometer display missing	Faulty display driver	Check IC2 (MM5450N)
	Faulty LED's	Check LED's

6 - Electronic Calibration Procedure

Before calibrating the electronic section of the Infant Flow™ Driver the power supply voltages should be checked. The reference and excitation voltages should be checked next and only then should the manometer and oxygen monitor sections be calibrated.

The equipment required for this is a good quality, calibrated DVM capable of resolving 10mV for checking the power supply rails, reference and excitation voltages and a 0 to 250 cm H_2O water column or similar accurate low pressure measuring device for calibrating the manometer and pressure relief valve. We do not recommend the use of mechanical pressure gauges for this purpose as they are inherently inaccurate. A hand pump bulb similar to those used on blood pressure sphygmomanometers is also required. To check and calibrate the oxygen monitor a supply of 4 bar pressure medical air and oxygen are required.

To gain access to the electronics it is necessary to remove the top cover from the Infant Flow™ Driver. This is achieved by removing the top two M3 raised countersunk screws on each side of the cover and then sliding the cover upwards and off. The adjustment trimmers are accessible at the top left of the electronics module. They may be adjusted from the side by using a standard trim tool.

To remove the manometer section completely it is advisable to remove the four M3 raised countersunk screws on the left hand side of the device and the four M3 x 8mm pan head screws on the back panel. This will enable the complete assembly to be slid forward so that the connectors can be removed from the bottom of the processor board (M672B) or the miniature D connector on the side of the module (M672P) to allow the assembly to be come out of the housing.

CAUTION: Disconnect the Infant Flow™ Driver from the external mains or 12VDC supply before attempting to remove the electronics module.

Power supply checks

To check the power rails it is advisable to first disconnect the power connector CON2 from the processor board. For the M672B ensure that the mains supply is connected to the mains input module and that the voltage selector is set to the correct value. Switch on the power to the unit. The voltage rails to be checked are:

The + 5VDC supply on pin 1 of CON2 with respect to 0V (Digital ground) on pin 2.

The +15VDC supply on pin 3 of CON2 with respect to 0V (Analogue ground) on pin 4.

The -15VDC supply on pin 5 of CON2 with respect to 0V (Analogue ground) on pin 4.

If these are all there, within 5% of their nominal value and stable the power supply is in good order. Disconnect the external power and reconnect CON2 to the processor board. Turn the power back on and continue to the next set of tests.

Display brightness set up

First the display brightness must be set. This is done by adjusting VR2 until the required brightness is obtained for the 7 segment displays and then adjusting VR1 until the bar graph LED's are of similar brightness. The light dependent resistor, LDR1, may be partially occluded to ensure that auto dimming is satisfactory.

Reference voltage checks

The reference voltage may now be checked. Connect the negative input of the DVM to the negative end of C17, and the positive input to TP6. A reading of 200mV ± 10mV should be indicated. The excitation voltage to the pressure transducer is checked on TP7 with reference to ground, this should be 12 ± 0.6V.

Manometer calibration

With no equipment connected to the pressure input set the manometer to zero with VR7. Connect the water column with the hand pump bulb into a "T" piece and into the manometer pressure input on the front panel. Inflate to 10 cm H_2O and observe that there are no leaks. Check that the manometer reads 10 cm H_2O, if not,

adjust VR3 to give the correct reading. Release the pressure and check that the zero reading has not changed. If it has, repeat the procedure until the readings are correct at both pressures. Pump the system up to 5 cm H_2O and ensure that the displayed value is 5 cm H_2O.

Once calibration is satisfactory pressurise the system to above 12 cm H_2O and ensure that all segments of the manometer bar graph illuminate, the high pressure LED is on, that the audible alarm sounds and the over-pressure relief solenoid is activated. Press the "MUTE" button and ensure that the audible alarm is silenced. Release the pressure in the system and press the "MUTE" button, the audible and visual alarms should cancel and the over pressure solenoid should de-activate.

Oxygen analyser calibration

M672B - There are two stages to the calibration of the oxygen analyser, first the calibration of the galvanic fuel cell itself and secondly the calibration of the mixer monitor which enables automatic alarm setting on the set value.

M672P – Has only one stage to calibrate the analyser, that being the galvanic fuel cell.

To calibrate the integral oxygen analyser the electronic module must be installed in the lower case with the leads connected to the mixer section of the driver. The Infant Flow™ driver must also be connected to a source of medical air and oxygen at 4 bar pressure. We recommend that a reference oxygen analyser with an accuracy of ± 1% is fitted in the outlet of the driver to verify the performance.

Set the flow to 8 lpm and turn the mixer control to 100% oxygen, ensure that the reference analyser is reading 100% oxygen. Adjust VR4 until 100% is displayed in the oxygen display window. Set the mixer control to 21% oxygen and ensure that the reference analyser reads 21% oxygen. Adjust VR8 until the oxygen display reads 21%. Repeat the process until no further adjustments are necessary.

On the M672B only it is necessary to calibrate the mixer monitor board. Ensure that the three way connector from the mixer control is connected to the processor board. Turn off the electronic module then press and hold the mute button whilst turning the power on again. The oxygen display will now show the setting of the mixer control. Set the mixer to 30% and adjust VR6 to give a display of 30%. Set the mixer control to 100% and adjust VR5 until 100% is shown. Repeat the process until no further adjustment is required. Check that at 60% the display reads 60 ± 2 digits. The Driver will return to normal operation after a period of 2 minutes has elapsed.

Once all of these procedures have been completed the Infant Flow™ Driver may be re-assembled.

7 - Mechanical Description

The mechanical section of the Infant Flow™ Driver consists of three major items; the enclosure, the air/ oxygen mixer and the Flowmeter/Pressure relief valve assembly.

The enclosure is fabricated from 2mm sheet Aluminium and is protected by a powder coat epoxy based paint which is very resilient to knocks and substances that may come into contact with it.

The Manometer section is held in the case by means of four M3 raised countersunk screws on the left hand side of the enclosure and four M3 x 8mm pan head screws with shakeproof washers on the back panel.

M672B - The mixer assembly is located by the two UNC screws that hold the pole mount bracket in place. The rear panel is locked in by the gas inlet mounting plate on the rear of the mixer.

The flowmeter mounting block fitted to the left hand side of the mixer routes all output gas from the mixer to the oxygen analyser and either the patient circuit or to atmosphere through the over pressure relief valve system. It is mounted on the mixer by two 8-32 UNC screws and the seal is made with an O-ring between two flat machined faces. This entire assembly may be removed for cleaning or repair by removal of these two screws.

M672P – The mixer is mounted on a bracket which is held by two M4 screws, one at the rear and one underneath the instrument, and directly onto the front panel by means of a locking nut. Do not remove the mixer from the front panel as this will cause calibration errors. The flowmeter block is mounted by means of two M4 screws under the instrument. Removal of these screws and the tie bar screw in the top left hand of the rear panel enables the complete flowmeter/mixer assembly to be withdrawn to facilitate oxygen sensor replacement.

The flowmeter is removed by loosening the M4 grub screw located on the left side of the assembly. Once loosened the flowmeter can be pulled forward and the tubing on the rear detached by pushing the blue ring in whilst pulling on the tubing. If removed, it is advisable to replace the O-rings prior to re-assembly.

The flowmeter should be cleaned if contaminated and the calibration should be checked periodically (annually if the supply gases are clean and dry). To clean the flowmeter, remove it from the block and disconnect the tubing by pushing the blue ring in towards the flowmeter whilst pulling on the tubing. Remove the nut on the top which allows the ball to be removed. Clean the tube with warm soapy water only, do not use spirit based cleaners as this will damage the acrylic.

Flowmeter Calibration Check

To check the flowmeter calibration attach the Infant Flow™ driver to the medical air and oxygen supplies and set the mixer to 50% oxygen. Connect the outlet of the Infant Flow™ Driver to a test flowmeter or flow test device with an appropriate hose. Select an indicated flow of 5 lpm on the Infant Flow™ driver flowmeter and verify that the correct flow is indicated on the test device within ± 10%. Repeat at 8, 10, 12 and 14 lpm.

Safety Pressure Relief Valve Setting

For the Infant Flow™ Nasal CPAP generator to function correctly it is necessary to have a back pressure of more than 10 times the required nCPAP pressure in the delivery circuit prior to the generator. For safety reasons the Infant Flow™ driver is equipped with two pressure relief systems. The first is a mechanical safety pressure relief valve designed to protect the equipment and delivery circuit. This is mounted on the flowmeter mounting block and is not accessible to the users. It is factory pre-set at 205 cm H_2O but should be checked whenever a performance verification is carried out.
To test the setting and efficacy of the safety pressure relief valve connect the calibrated water column or similar pressure measuring system into the patient circuit. Set a flow of 8 lpm on the flowmeter and occlude the delivery tube. The pressure in the patient circuit should reach 205 cm H_2O ± 20 cm H_2O. If necessary, adjust the safety pressure relief valve to give a reading of 205 cm H_2O on the water column.

The second safety relief valve is to protect the patient and consists of an electronic solenoid valve which operates when the measured pressure in the patient circuit exceeds 11 cm H_2O. Gas from the mixer is passed through a fixed regulator and the solenoid valve and acts on a silicone diaphragm located under a plate on the flowmeter mounting block. When an over pressure is detected the solenoid is activated and the pressure removed from the diaphragm. This allows the gas in the patient circuit to vent to ambient and reduces the pressure in the patient circuit to virtually zero instantaneously.

It is necessary to check the pressure setting of the electronic safety system periodically. This is achieved by disconnecting the tube from the pressure regulator to the solenoid valve and connecting to an accurate pressure measuring device such as a mercury column. The regulator should be set for between 160 & 180 mm Hg. Once tested and set replace the tube on the solenoid and check the function of the electronic over pressure vent valve.

Oxygen sensor

The sensor for the oxygen monitor is a Teledyne R22 or equivalent electro-chemical galvanic fuel cell. It is mounted on the flowmeter mounting block directly behind the flowmeter. It is supplied with a continuous flow of fresh mixed gas from the mixer through a flow limiting device which eliminates any pressure variation thus ensuring speed and accuracy. The sensor has an average life of one year. The end of life indication for this sensor is when it is no longer possible to calibrate it accurately, however, it is recommended that it is replaced annually.

Air/Oxygen Mixer

M672B - The integral air/oxygen mixer is a derivative of the Sechrist model 3500.
M672P - The integral air/oxygen mixer is a derivative of the Bird Products, Low Flow Micro Blender.

If the criteria for the gas supplies are met and the supplies are satisfactorily clean and dry, both types of mixer will provide years of reliable use with relatively little care and service.

As both types of air/oxygen mixer require special fixtures, jigs and tools to effect repair EME recommend that only minor work such as filter and one way valve replacements are made on site. Therefore the instructions in this manual are limited to testing for proper operation and troubleshoot malfunctions.

A service exchange system for major modules or complete mixers is in operation either directly with EME or through an appointed distributor.

Auxiliary Mixed gas outlets

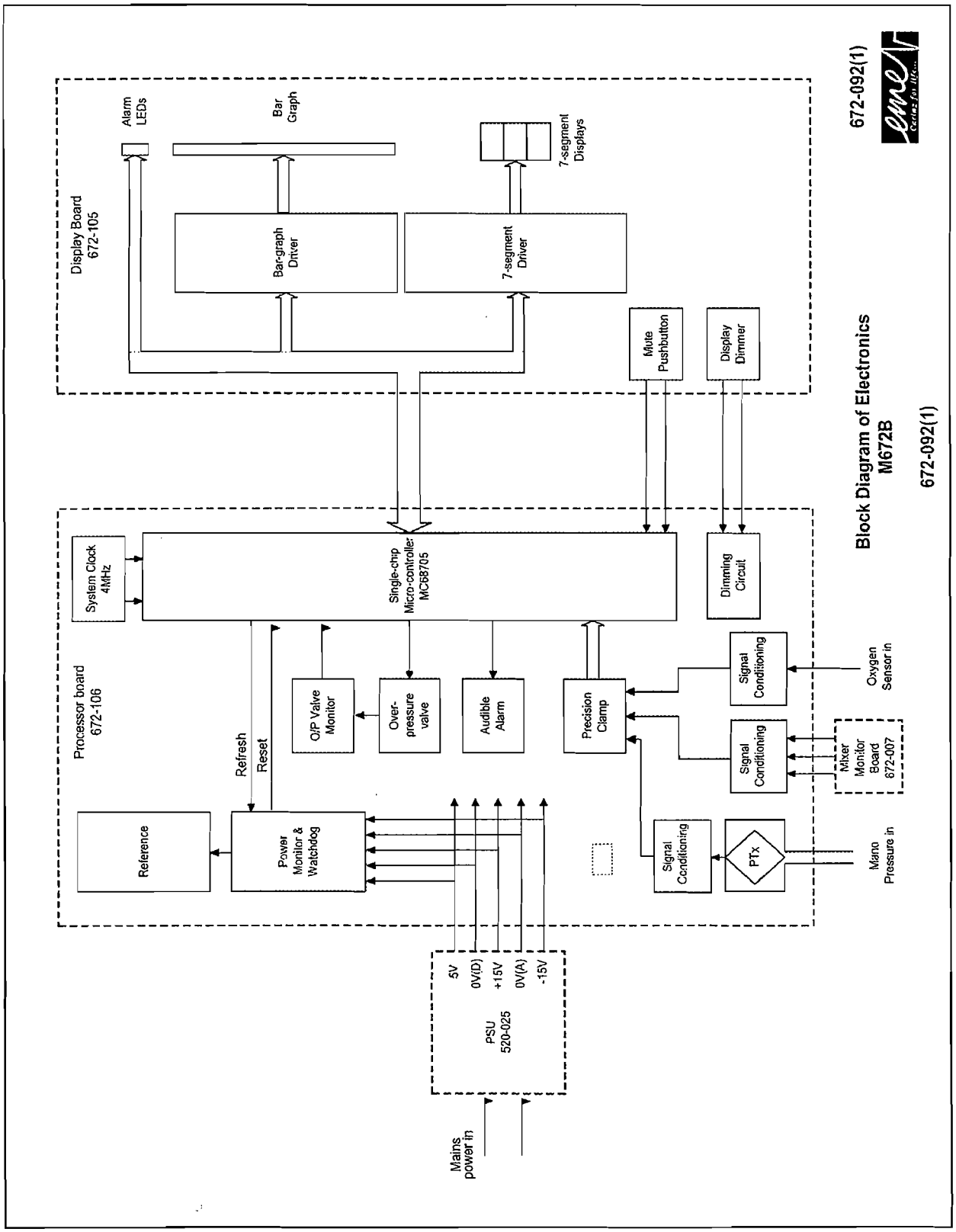
Two types of auxiliary mixed gas outlet are offered on the M672P both of which are optional. These are either a front panel mounted quick connect style with an adjusting regulator and guage (mounted on rear panel) or a side mounted DISS with check valve for the attachment of a standard flowmeter.

The M672B has the option of either a DISS with check valve or a mini-schrader mounted on the underside of the device adjacent to the patient outlet.

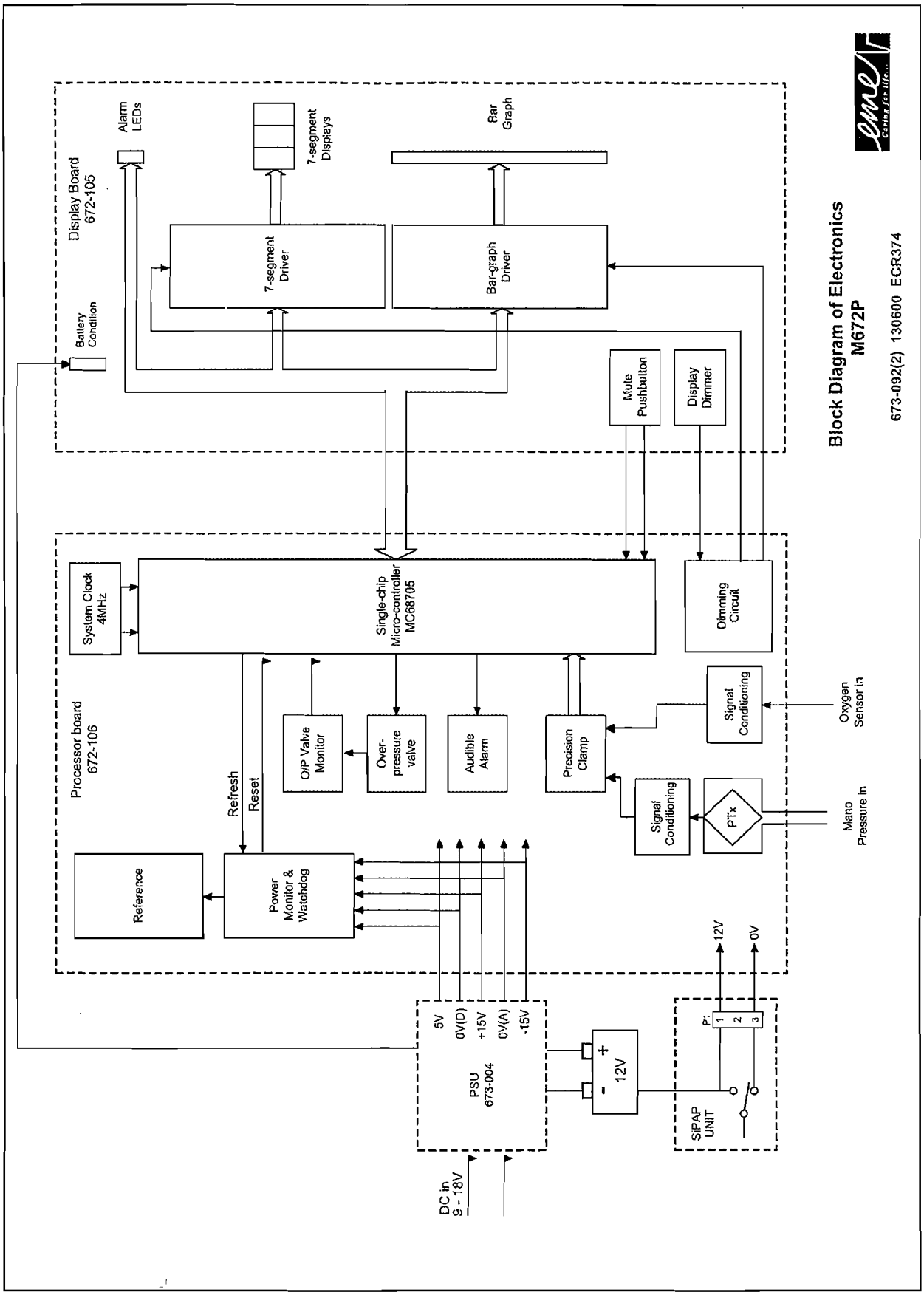
Please refer to the operation and routine maintenance manual for the limitations and special precautions required for the use of each of these outlets.

Oxygen Mixer - Trouble Shooting Guide		
Problem	Possible cause	Corrective action
Delivered oxygen concentration incorrect	Oxygen sensor calibration incorrect (most common problem)	Re-calibrate oxygen analyser
	Improper purity of supply gases	Check quality of gas supply
	Wrong gas supplied to inlet	Assure outlets and hoses are correct
	Front or rear seats worn	Replace proportioning valve module or mixer
	Calibration of proportioning valve incorrect	Replace proportioning valve module or mixer
	Pressure balancing module malfunctioning	Replace pressure balancing module or mixer
Control knob is hard to turn	Knob has been knocked bending adjuster shaft	Replace proportioning valve module or mixer
Delivered oxygen concentration change is < 2% when testing	Air or oxygen inlet filter occluded causing > 1.3 bar differential pressure	Replace inlet filters
	Regulator needle(s) out of calibration	Replace proportioning valve module or mixer
	O-rings on regulator seat damaged causing leak	Replace proportioning valve module or mixer
	Contamination from supply gases	Replace mixer
Continuous alarm with both inlet pressures equal	Dirty inlet filter(s)	Replace inlet filters
	Alarm module adjustments out of calibration	Replace alarm module or mixer
Alarm not sounding with the loss of one gas	Defective reed	Replace reed alarm assembly
	Alarm module adjustments out of calibration	Replace alarm module or mixer

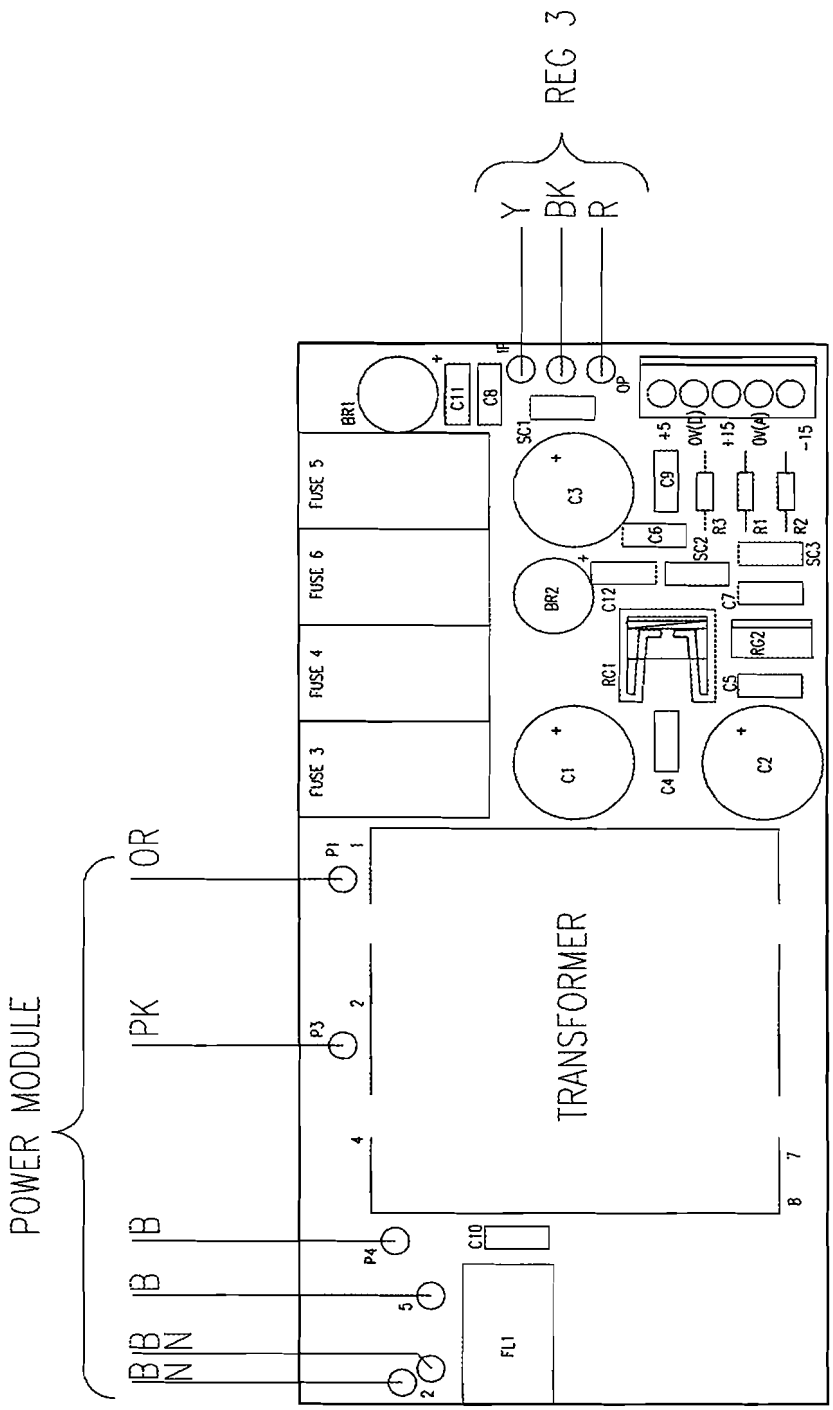
Appendix A - Circuit and Layout Diagrams



Drawing No: 672-092, M672B Electronics Block Diagram

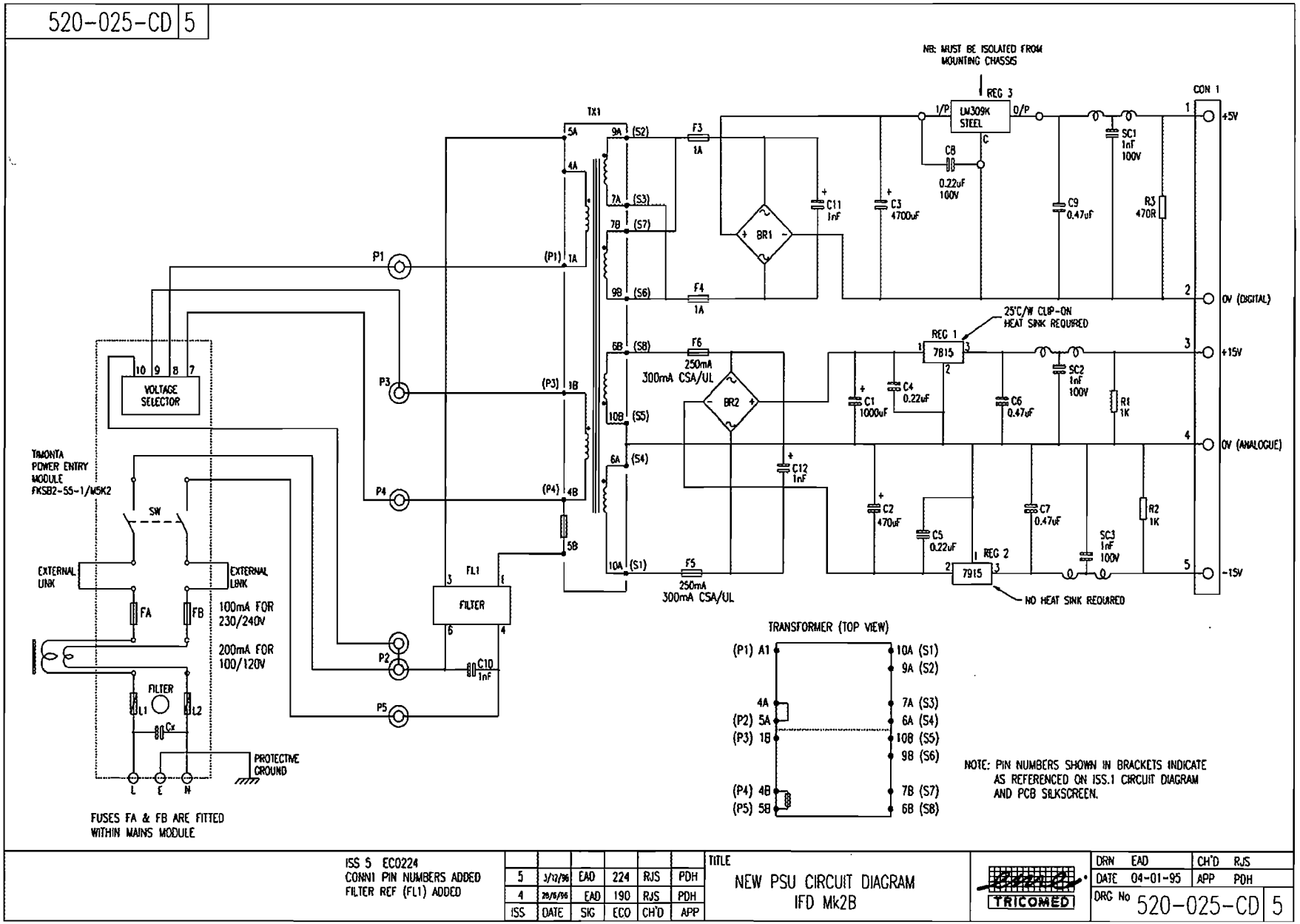


Drawing No: 673-092, M672P Electronics Block



Drawing No: 520-025A, M672B Power Supply PCB Layout

Drawing No: 520-025-CD, M672B Power Supply Circuit Diagram



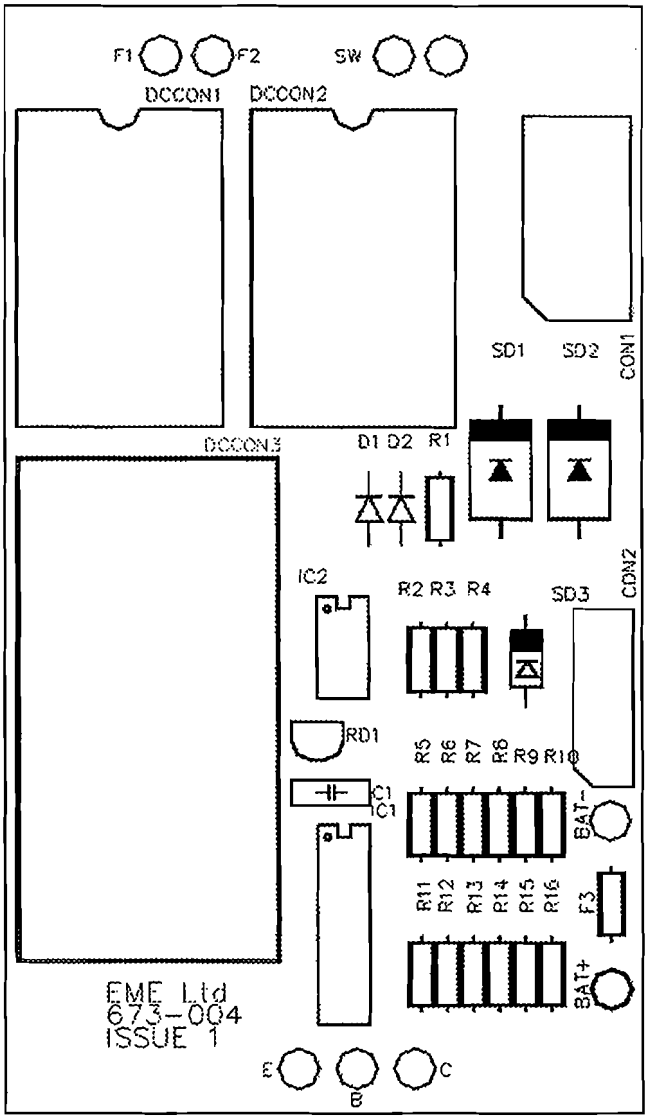
ISS	DATE	SIG	ECO	CH'D	APP
5	3/12/96	EAD	224	RJS	PDH
4	26/6/96	EAD	190	RJS	PDH

ISS 5 ECO224
CONN1 PIN NUMBERS ADDED
FILTER REF (FL1) ADDED

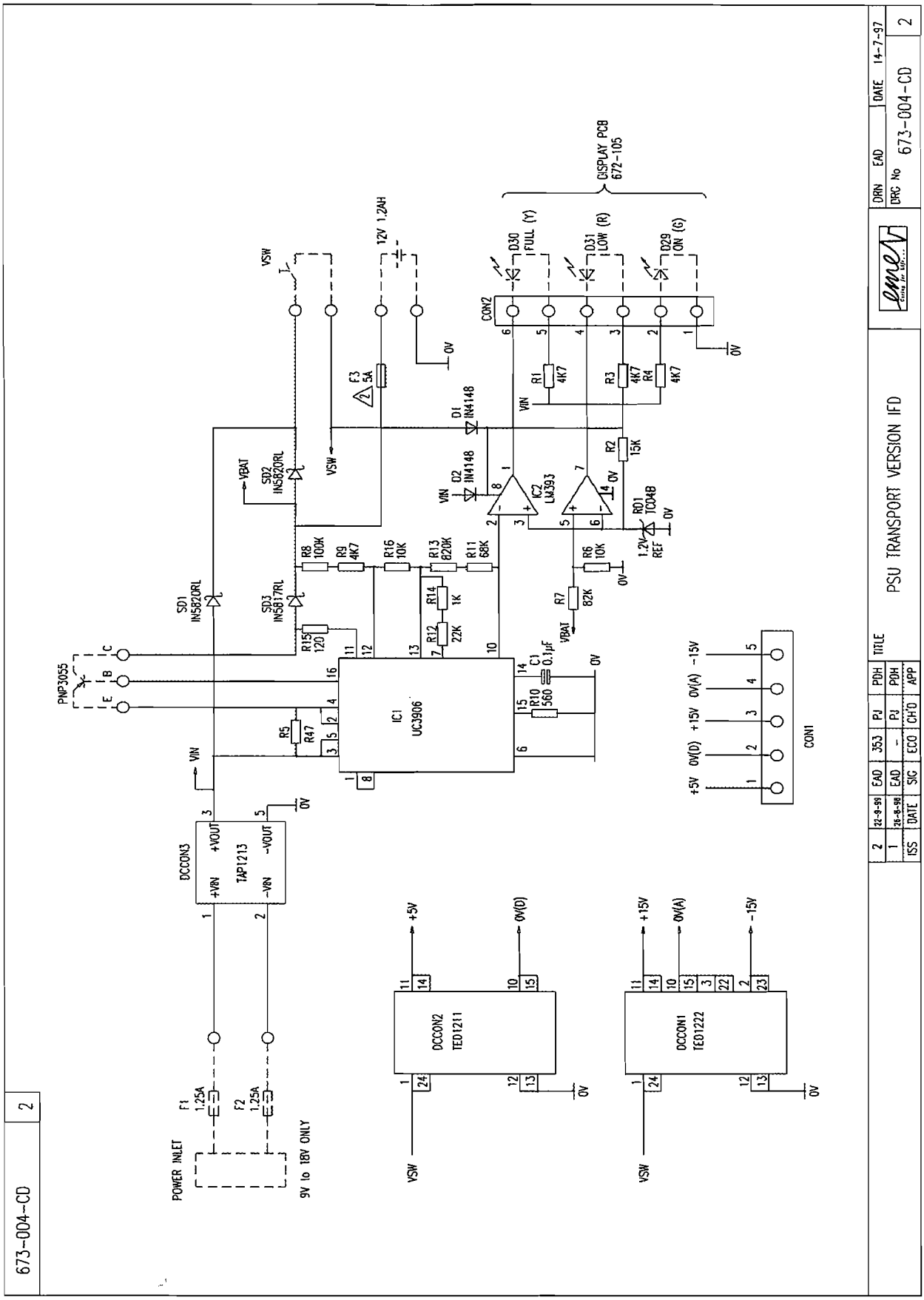
TITLE: NEW PSU CIRCUIT DIAGRAM IFD Mk2B

TRICOMED

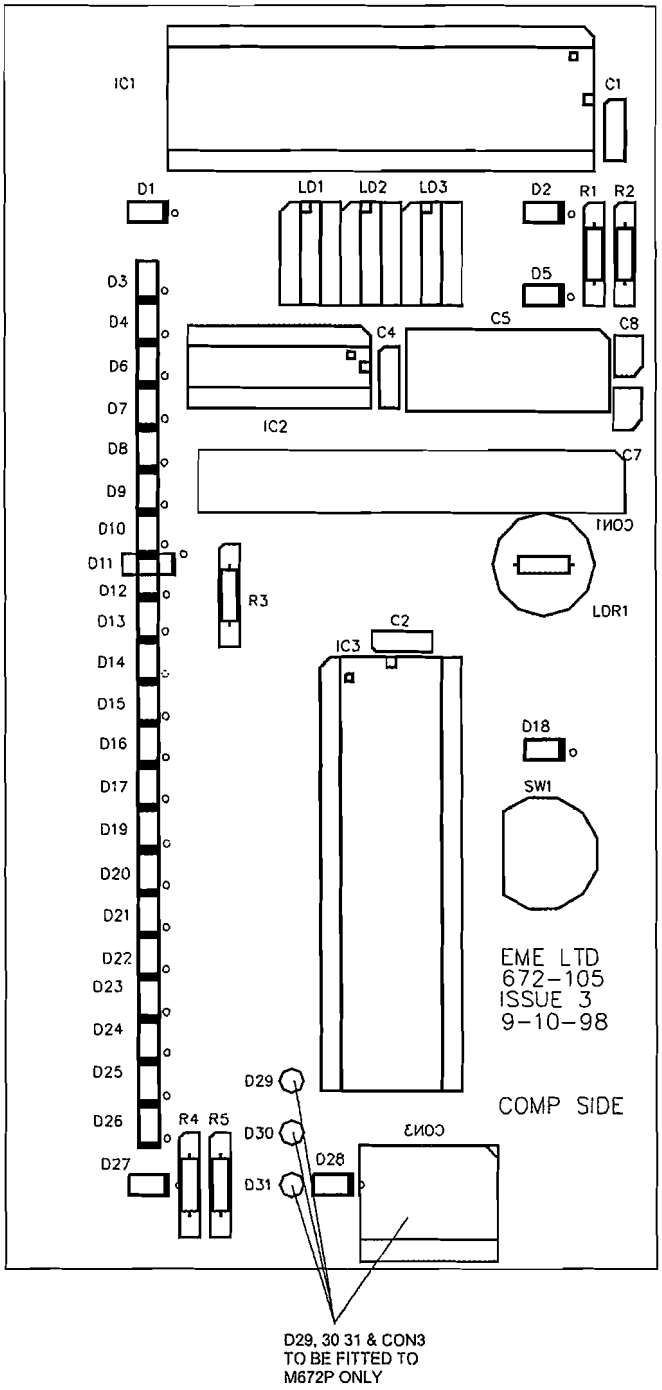
DRN	EAD	CH'D	RJS
DATE	04-01-95	APP	PDH
DRG No	520-025-CD		5



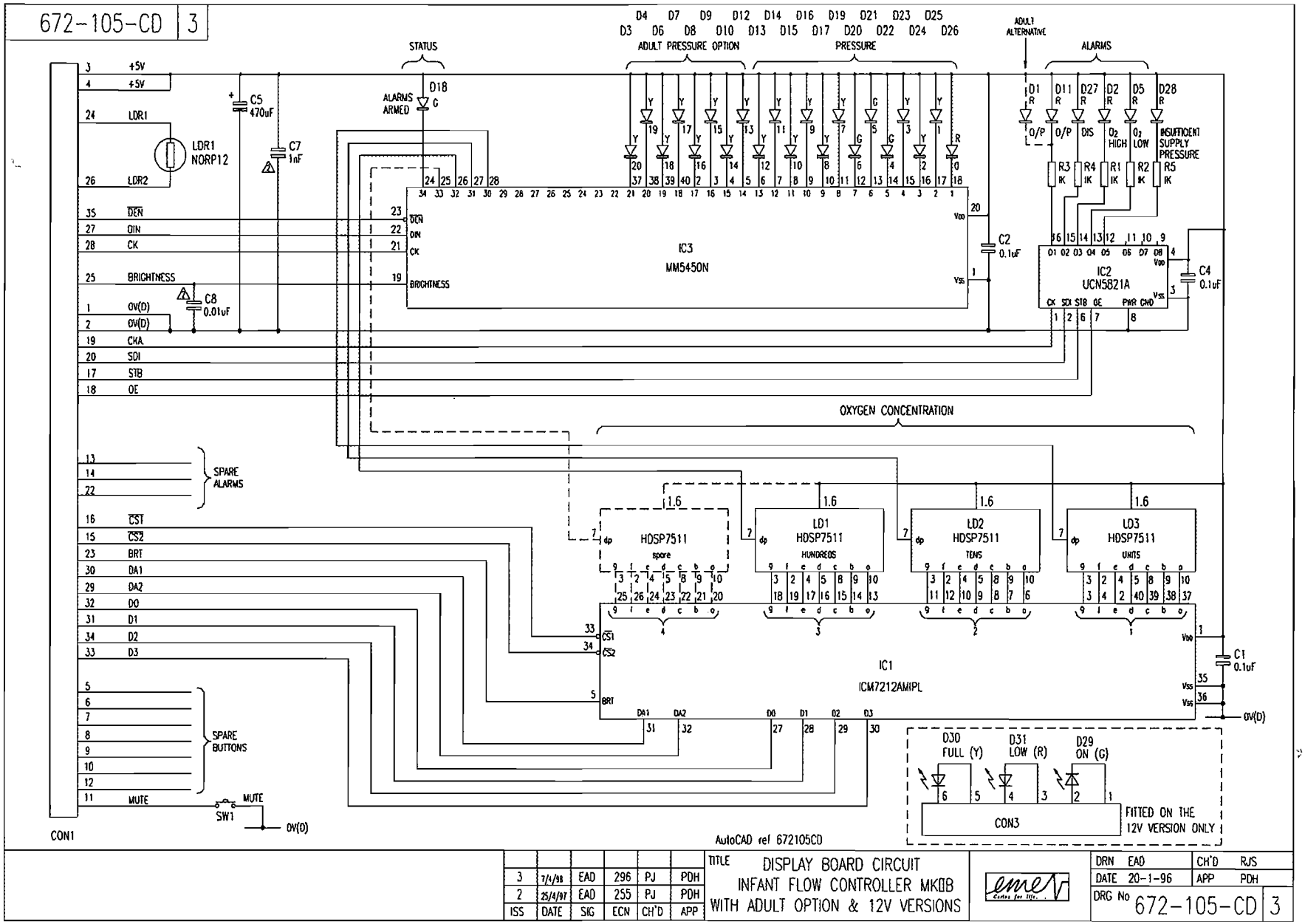
Drawing No: 673-004, M672P Power Supply PCB Layout



Drawing No: 673-004-CD, M672P Power Supply Circuit Diagram



Drawing No: 672-105, Display Board PCB Layout

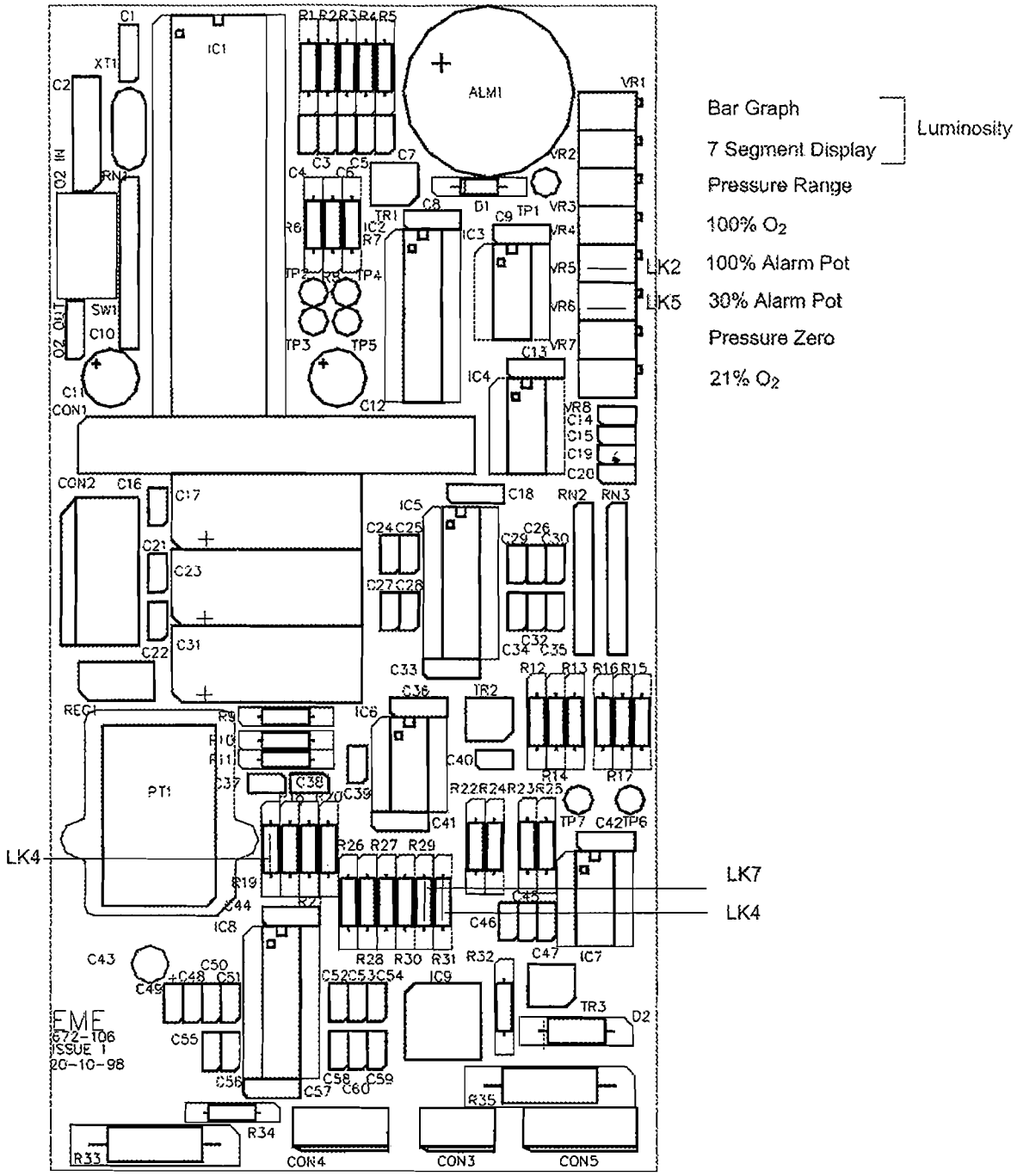


ISS	DATE	SIG	ECN	CH'D	APP
3	7/4/98	EAD	296	PJ	PDH
2	25/4/97	EAD	255	PJ	PDH

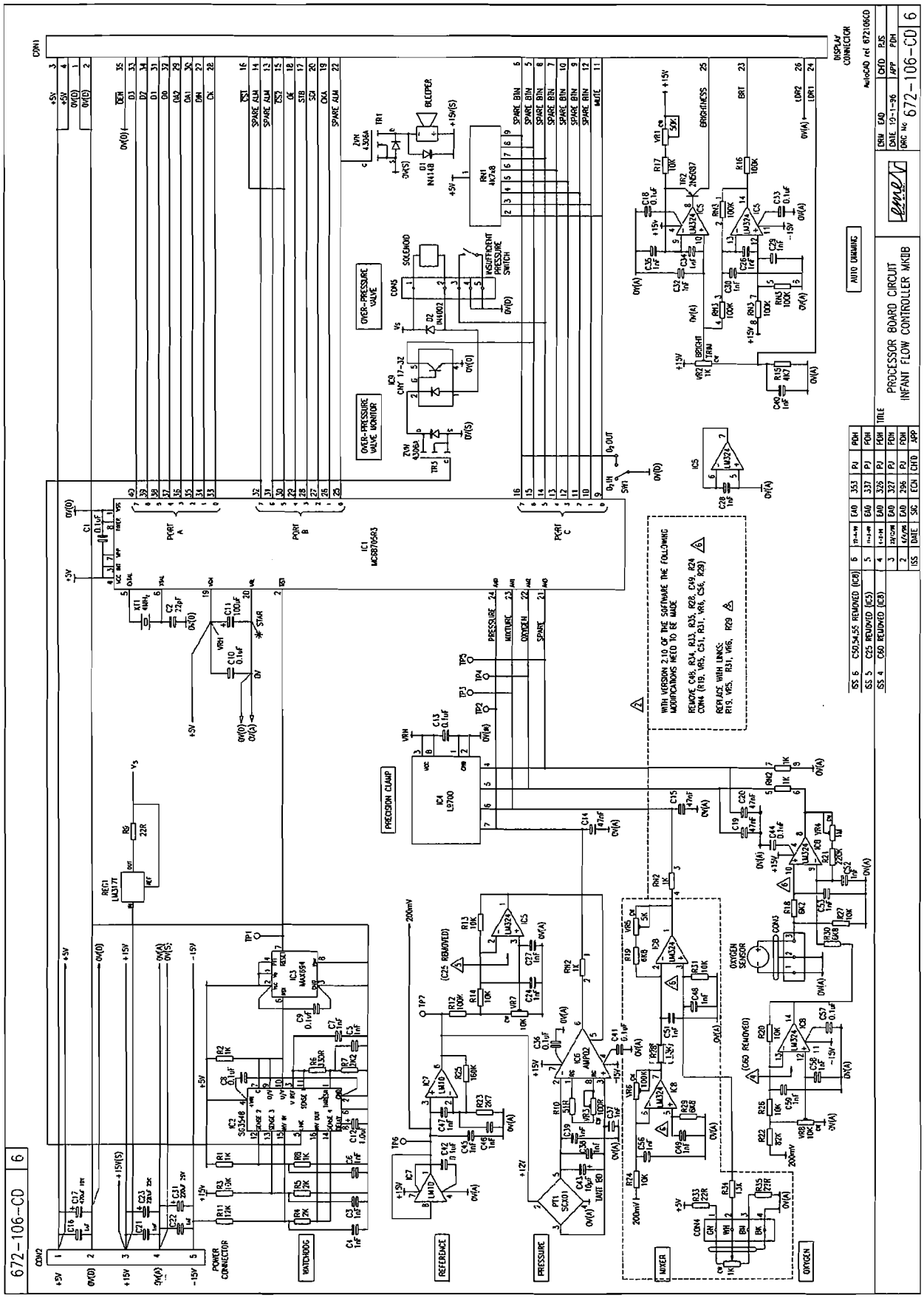
TITLE DISPLAY BOARD CIRCUIT
INFANT FLOW CONTROLLER MKIIB
WITH ADULT OPTION & 12V VERSIONS

DRN	EAD	CH'D	RJS
DATE	20-1-96	APP	PDH
DRG No	672-105-CD		3

Drawing No: 672-105-CD, Display Board Circuit Diagram

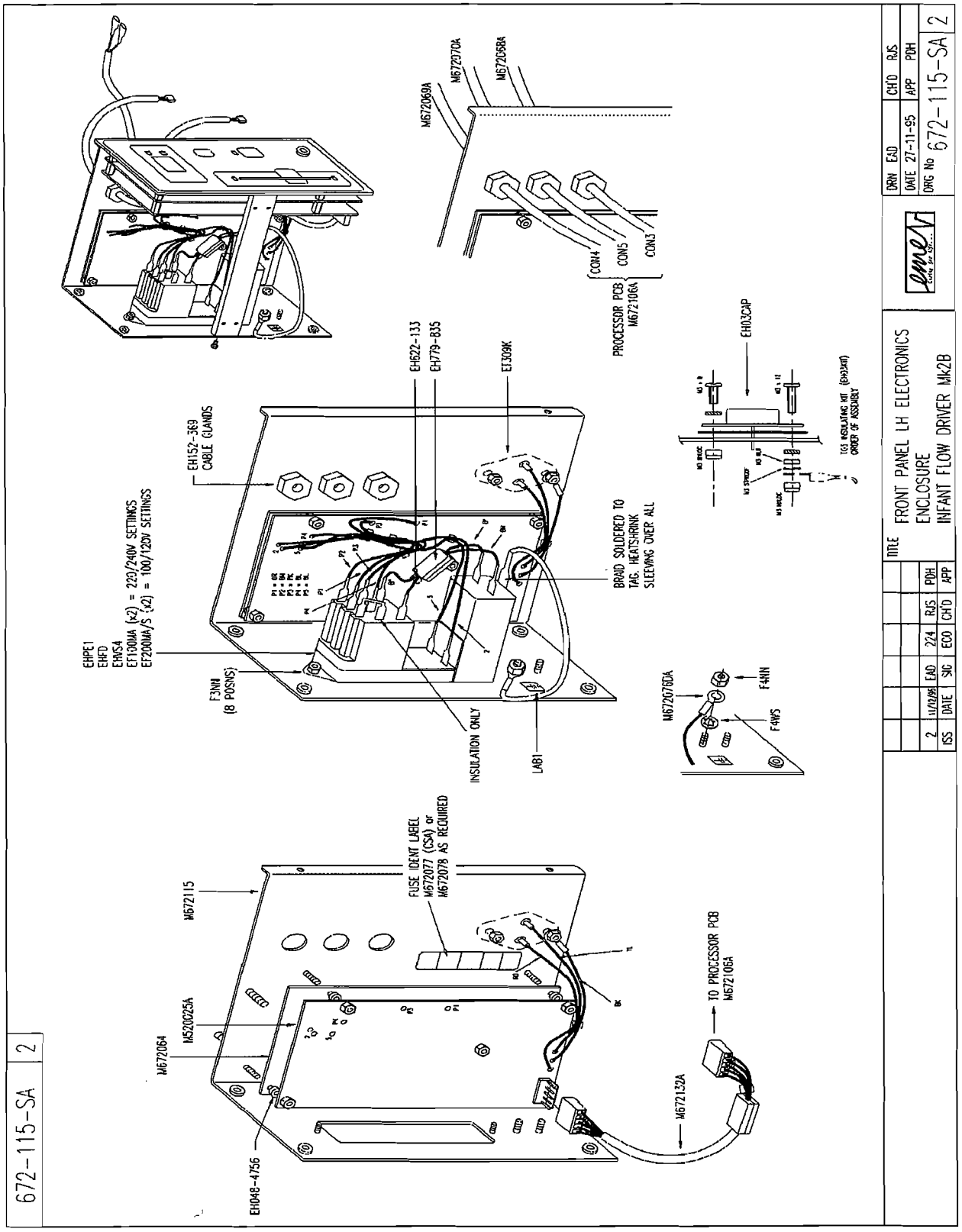


Drawing No: 672-106, Processor Board PCB Layout

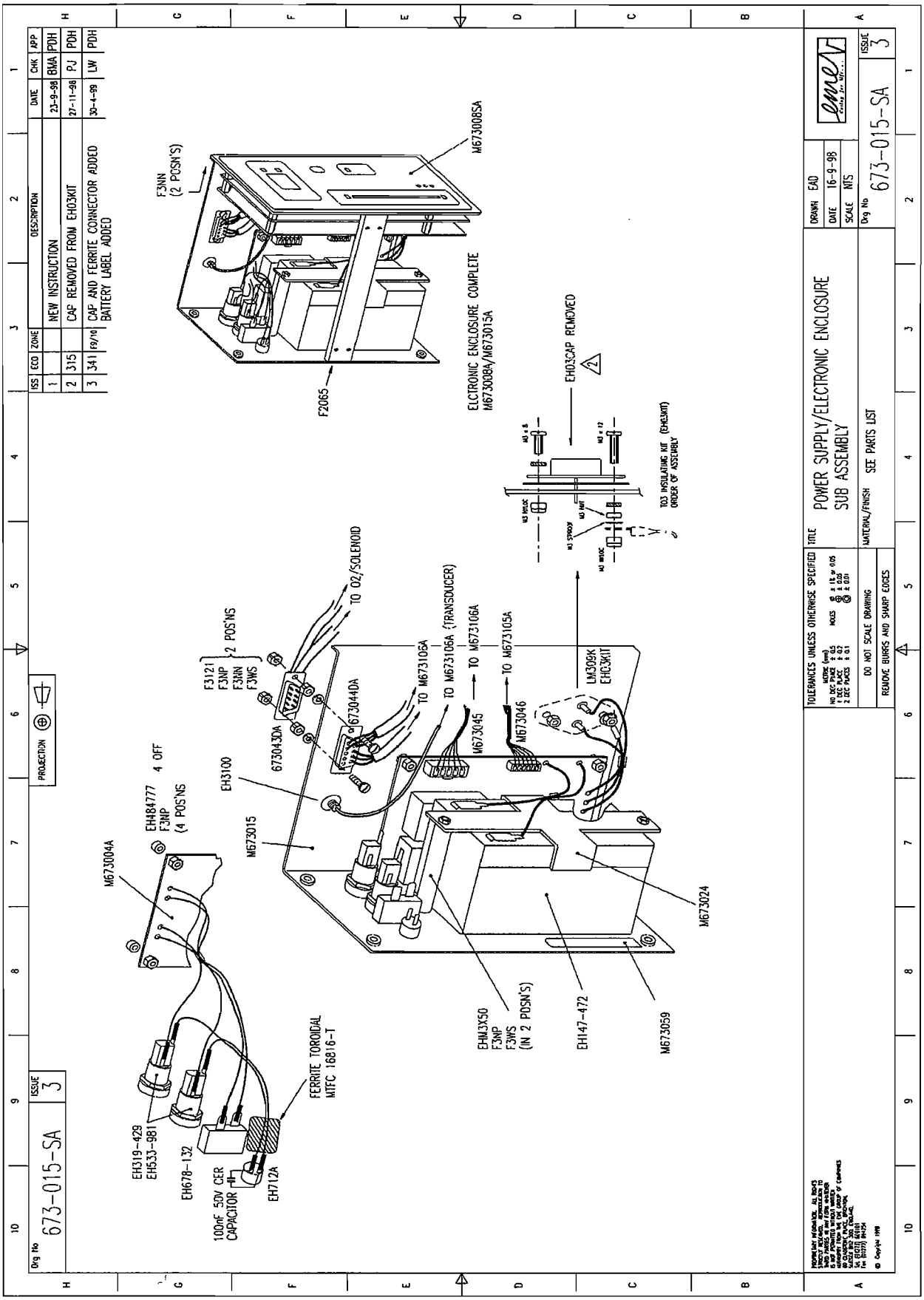


Drawing No: 672-106-CD, Processor Board Circuit Diagram

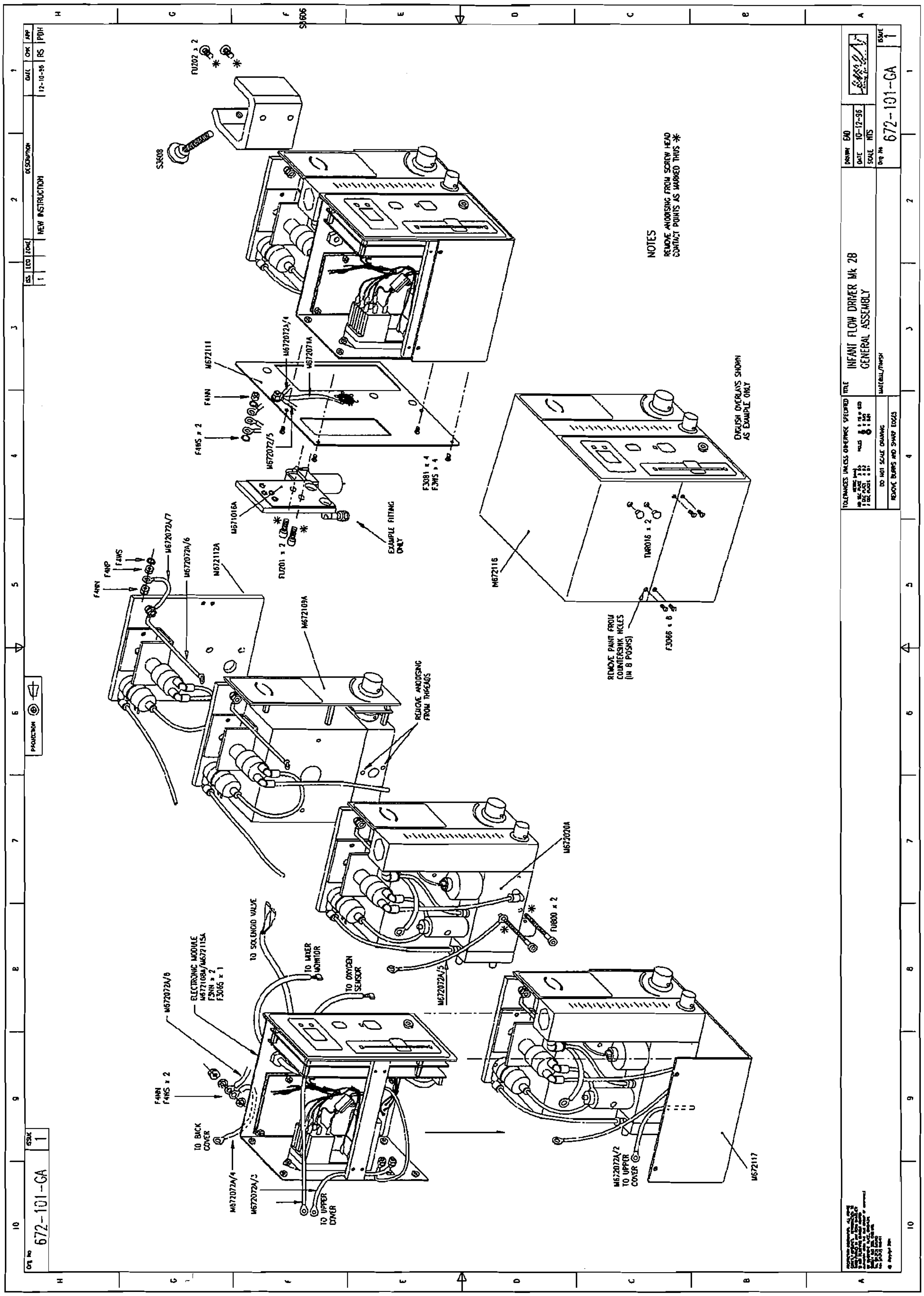
Appendix B - Mechanical Drawings



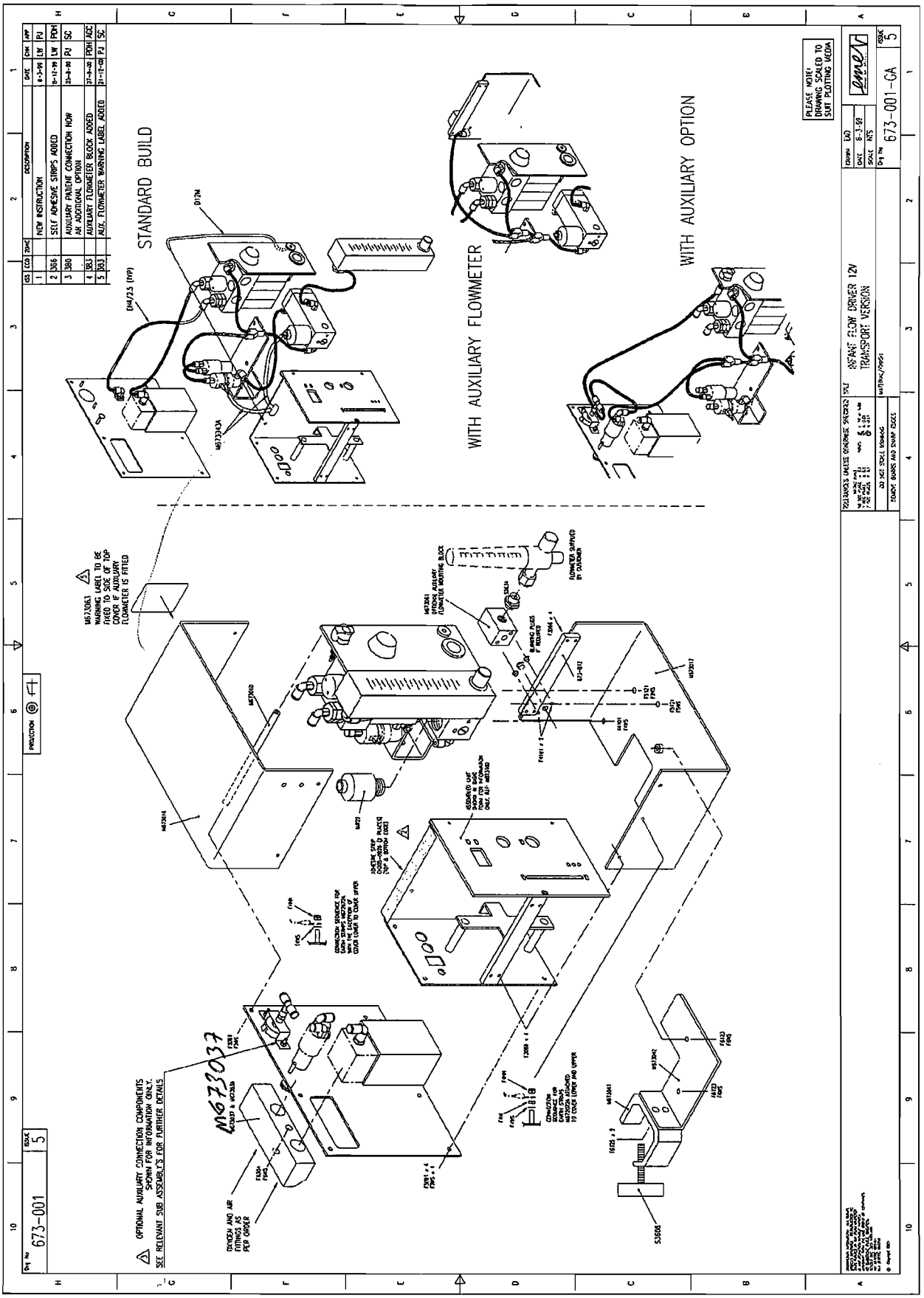
Drawing No: 672-115-SA, M672B Electronic Enclosure Assembly



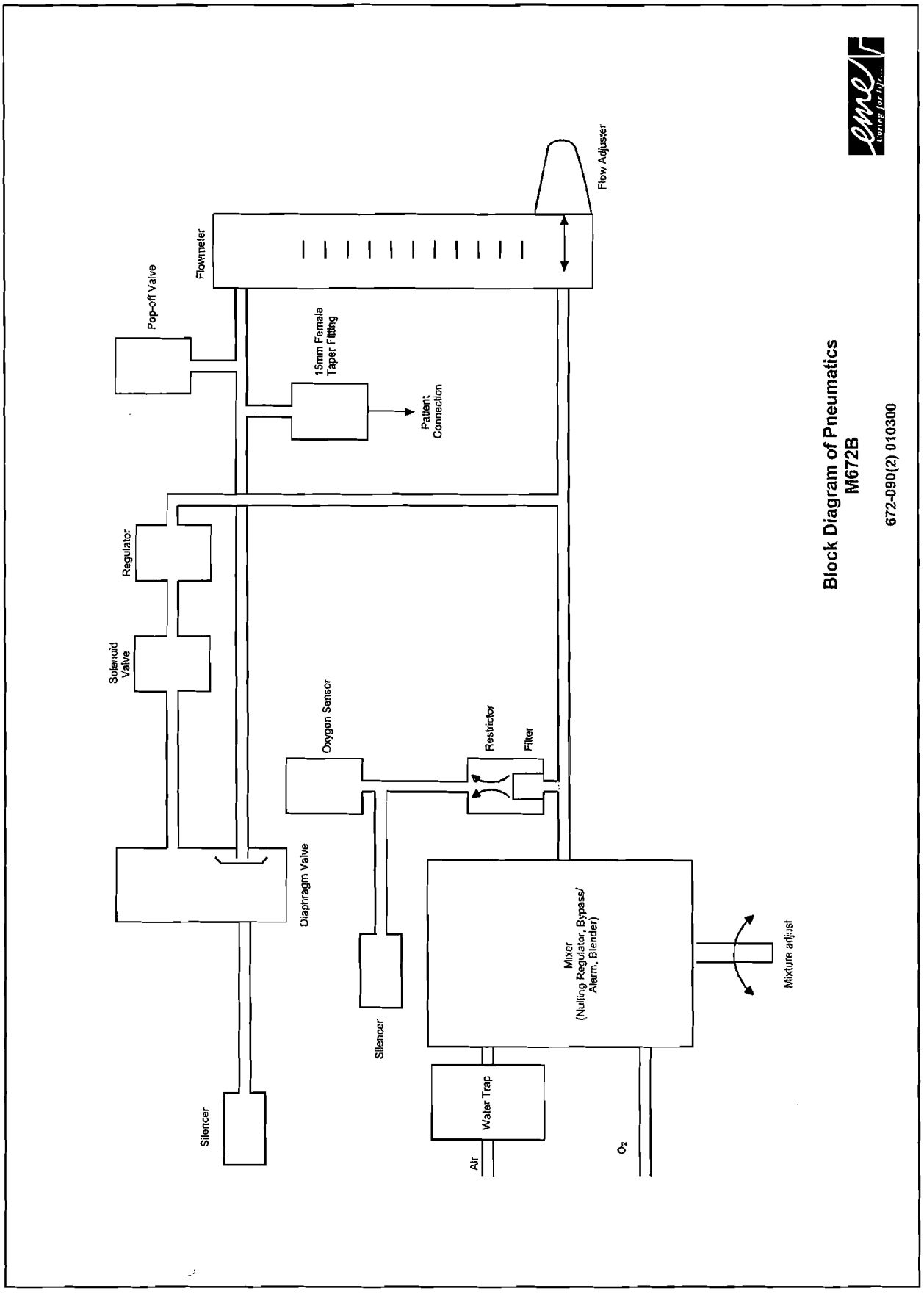
Drawing No: 673-015-SA, M672P Electronic Enclosure Assembly



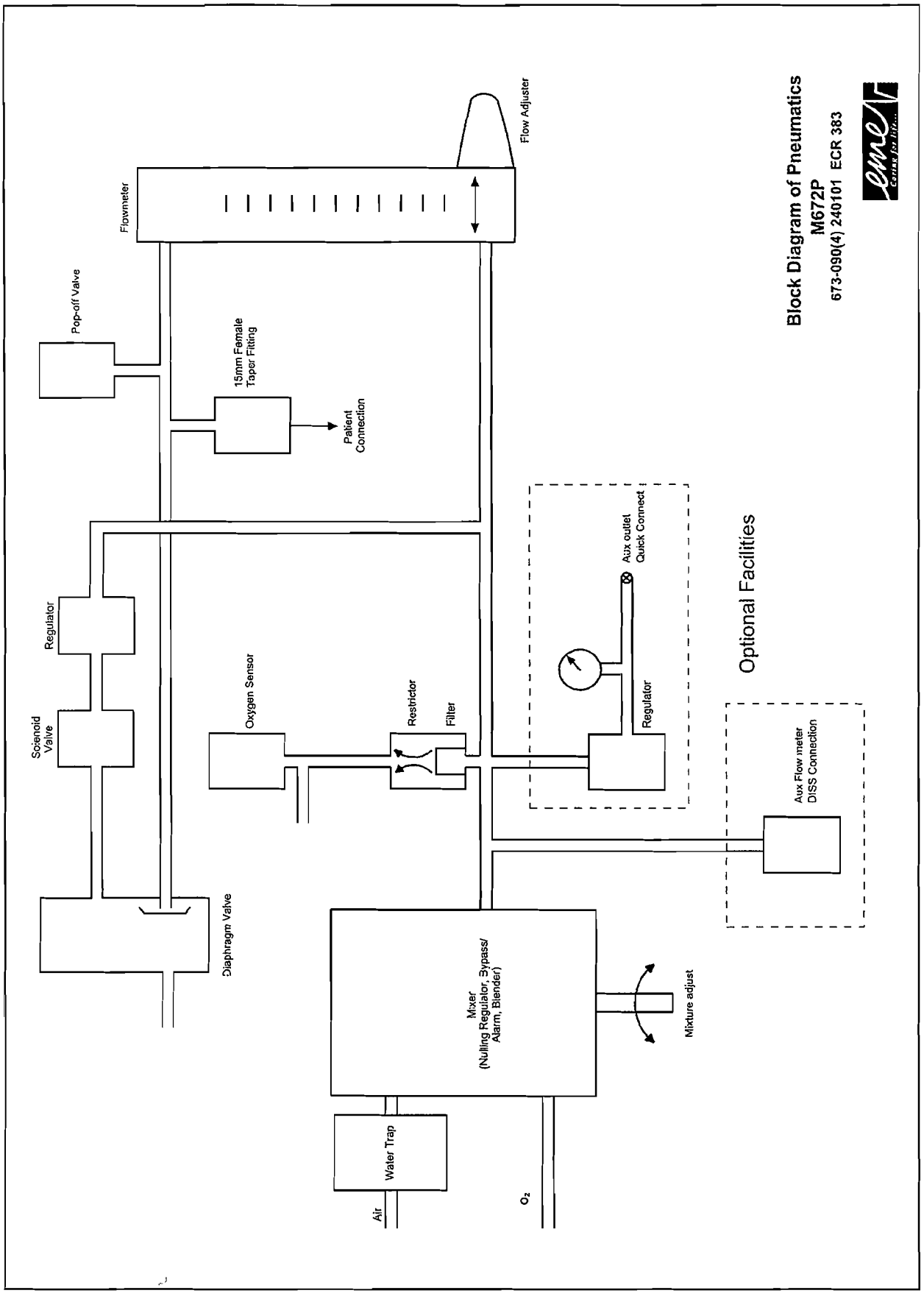
Drawing No: 672-101-GA, M672B General Assembly



Drawing No: 673-001GA, M672P General Assembly



Drawing No: 672-090, M672B Pneumatics Block Diagram



Drawing No: 673-090, M672P Pneumatics Block Diagram

Appendix C, Information on Oxygen Fuel Cells

Material Safety Data:

Product Name: Class R-22TED Oxygen sensor

Physical & Chemical Data: Granular Potassium Hydroxide (KOH) 15% and pure Lead (Pb)

Health Hazard Data:

Primary routes of entry: Ingestion, Eye/Skin Contact.

Exposure limits: OSHA PEL .05 mg/cu m (Pb)
ACGIH TLV 2 mg/cu m (KOH)

Effects of Over-exposure:

Ingestion: The electrolyte could be harmful or fatal if swallowed.

Eye: The electrolyte is corrosive, eye contact could result in permanent loss of vision.

Dermal: The electrolyte is corrosive and skin contact will result in chemical burn.

Inhalation: Liquid inhalation is unlikely.

Signs/Symptoms of exposure:

Contact with skin or eyes will cause a burning sensation and/or a soapy feeling for skin contact.

Emergency and First Aid procedures:

Eye Contact: Flush with water for at least 15 minutes and get immediate medical attention.

Skin Contact: Wash affected area with plenty of water and remove contaminated clothing. If burning persists seek medical attention.

Ingestion: Give plenty of cold water - do not induce vomiting, get medical attention.

Handling Information:

Handling precautions: The oxygen sensors are sealed and under normal circumstances the contents of the sensors do not present a health hazard. The following information is given as a guide in the event that a cell leaks.

Protective clothing: Rubber gloves, chemical splash goggles.

Clean-up procedure: Wipe down the area several times with a wet paper towel. Use a fresh towel each time.

Protective measures during cell re-placement:

Before opening the bag containing the cell, check the cell for leakage. If the cell leaks do not open the bag. If there is liquid around the cell while in the instrument put on gloves and eye protection before removing the cell.

Disposal:

In accordance with all applicable state, local or federal regulations.

Appendix D - Spare Parts List

Part No	Description
M672102	Electronic module 100/260 VAC 50/60Hz, M672B
M672105A	Display board assembly, M672B
M672106A	Processor board assembly (less CPU), M672B
M672007A	Mixer monitor board assembly, M672B
M672108A	Left hand front panel assembly, M672B
M672109A	Right hand front panel assembly, M672B
M672018	Left hand overlay, M672B
M672019	Right hand overlay, M672B
M672020A	Flowmeter mounting block assembly, M672B
M672024A	7 micron filter/restrictor assembly
M672025A	Mixer shaft adaptor assembly, M672B
M672050	Oxygen calibration label
M673029	Pop-off valve assembly
M70BS	Precision regulator
MET03	Solenoid valve type ET03
MR22	Telydyne R22 oxygen fuel cell
M673102	12 VDC electronic module , M672P
M673004A	Power supply board assembly, M672P
M672105PA	Display board assembly, M672P
M672106PA	Processor board assembly, M672P
M672SKIT	Annual maintenance kit, M672B
S3522K	7 Micron sintered steel filter kit for Sechrist mixer, M672B
M672PSKIT	Annual maintenance kit, M672P
B06804	Nylon cone filter for Bird mixer, M672P
M1129116A	5 Micron filter for watertrap, M672B
M9251708	5 Micron filter for watertrap, M672P
EH147-472	12 VDC lead acid battery
M954097 or MWSA112UM	AC Adaptor, 95 to 260 VAC, UK
M954092 or MWSA112EM	AC adaptor 95 to 260 VAC, Europe
MWSA112NM	AC adaptor 95 to 260 VAC, USA
MWSA112AM	AC adaptor 95 to 260 VAC, Australia
Call for info	AC Adaptor, lead to lead style

Appendix E - Warranty and Disclaimer

WARRANTY

This is the standard warranty for all products manufactured or supplied by E.M.E. (Electro Medical Equipment) Ltd. (hereinafter referred to as EME) and is extended only to the buyer purchasing the said product directly from EME or from an authorised dealer, distributor or agent as new merchandise.

All products supplied by EME are warranted for a period of one year from the date of installation or eighteen months from the date of delivery (whichever comes sooner) to be free from manufacturing defects and to conform to the description thereof contained in the relevant Operation and Routine Maintenance Manual, except that such warranty is limited to thirty (30) days with respect to rubber goods.

EME's sole obligation under this warranty is limited to the replacement or repair of the product or parts thereof which upon examination are found to contain manufacturing defects or not to conform to the description thereof contained in the relevant manual. EME will not be liable for consequential damages.

The foregoing warranty shall not apply if the product or any part thereof has (i) been repaired or altered by anyone other than an authorised representative of EME without written consent (ii) subjected to abuse, misuse, negligence or accident (iii) operated under conditions other than normal use (iv) the prescribed periodic maintenance and/or services have not been performed as specified in the relevant manual.

There are no warranties which extend beyond this warranty and the description of the products contained in the relevant Operation and Routine Maintenance Manual. EME makes no warranty as to merchantability with respect to the products. This warranty is given in addition to statutory warranty and in no way affects the purchaser's statutory rights.

DISCLAIMER

The EME guarantee will only be effective on condition that the product is used for the specific intention for which it was designed and operated as given in the Operation and Routine Maintenance Manual. Any reuse of single use products, or use of the equipment in conjunction with, or whilst attached to non-approved equipment will automatically void any guarantee or warranty in force. EME will not accept any liability for any injury or damage to persons or property resulting from a breach of these conditions. EME will only guarantee product supplied if it has been serviced in accordance with procedures given in the Service Manual, by hospital service personnel or authorised representatives who have been trained by EME and providing that the product has not been modified, altered or changed unless specifically authorised to do so in writing by EME.